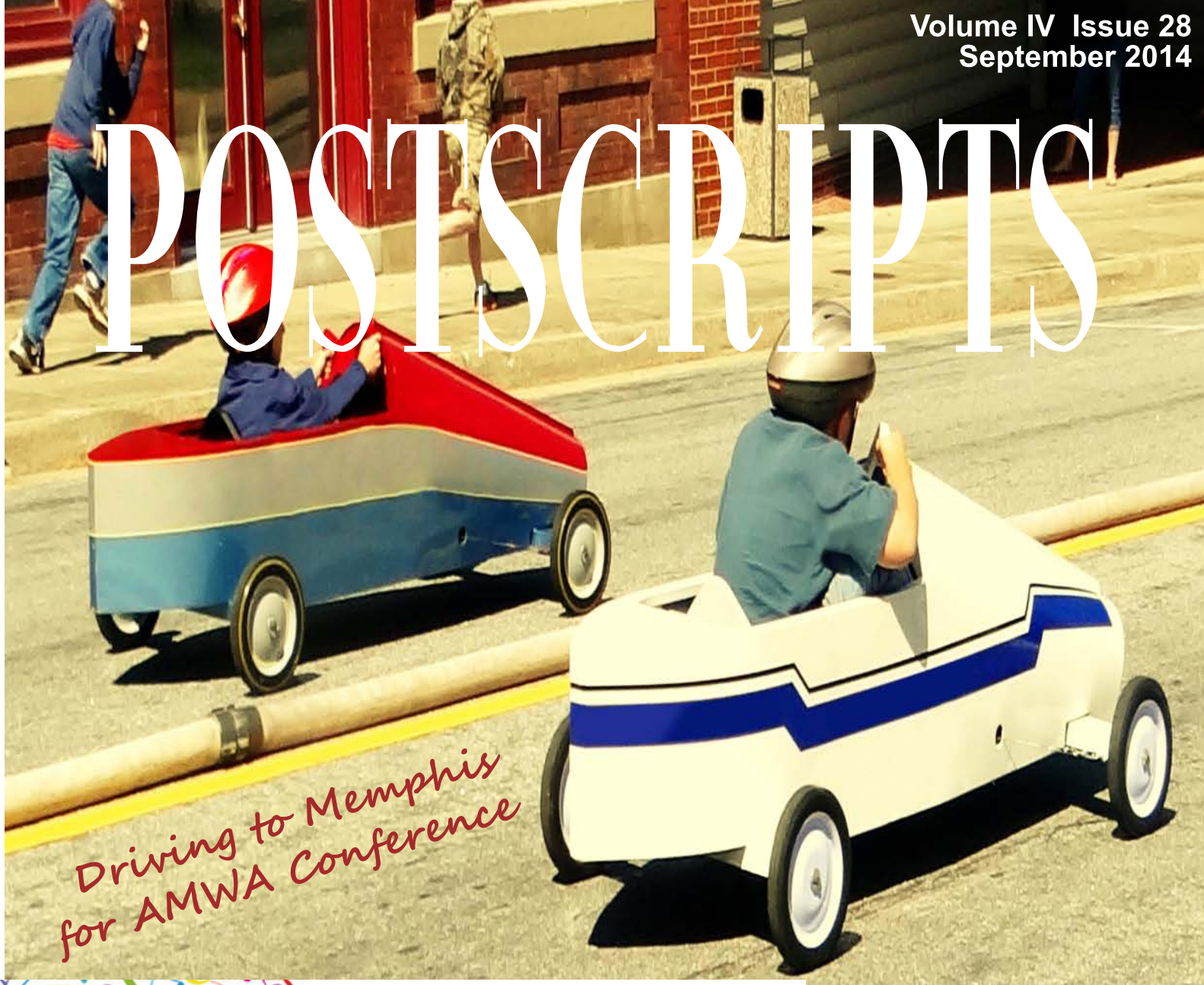
Volume IV Issue 28
September 2014

POSTSCRIPTS



Driving to Memphis for AMWA Conference

in this issue

Official publication of the American Medical Writers Association Pacific-Southwest Chapter

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering Chapter activities.

Postscripts Website:
http://issuu.com/postscripts

Chapter Website:
www.amwa-pacsw.org

Find us at LinkedIn Groups:
click *here*

SUBSCRIPTION

Postscripts is published monthly except in January and July. Subscription is included in the AMWA Pac-SW chapter membership which is automatic for all AMWA members with a mailing address in Southern California, Southern Nevada and all of Arizona. This newsmagazine is distributed on the 1st of each month.

INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

American Medical Writers Association
Pacific Southwest Chapter
(AMWA Pac-SW)
San Diego, CA
www.amwa-pacsw.org

Banner Photo Art by Chip Reuben, www.photoartwindows.com / Red phone booth. By Petr Kratochvil, publicdomainpictures.net

POSTSCRIPTS

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in this issue. . .

CHAPTER EVENTS AND NOTICES

September 12, 2014, Tuesday, San Diego, CA. Association of Clinical Research Professionals (ACRP) Fall Symposium – AMWA will host joint panel discussion at the Fall Symposium about Protocol Design and Development. Susan Vintilla-Friedman presenting on behalf of AMWA.

September 20, 2014, Saturday: AMWA-SDRAN Joint Meeting. Susan Chang from our Chapter will discuss Advanced Techniques and Best Practices for Document Preparation. To register for the meeting, go to https://www.123signup.com/event?id=yzfrp

October 2, 2014, Tuesday: Free Chapter Webinar (1 hour). Lauren Sobocinski and Valerie Breda from Synchrogenix to present what medical writers should consider for the Request for Proposal process. – Details to follow.

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From the President's Desk

"Rhythm is something you either have or don't have
but when you have it, you have it all over."
—Elvis

Hi everyone,

Are you ready for some shaking, rattling and writing? Our annual AMWA meeting is just a month away in Memphis! Our newsmagazine Editor, Ajay, has provided a nice overview of the workshops and open sessions available at the Annual meeting. If you see one of our new members at the annual meeting or at one of our upcoming Chapter events, please introduce yourself and welcome them to our Chapter.

To help get ready for the annual meeting, we have 3 great events planned over the next month. September 12th is a joint panel discussion about Protocol Design at the Association of Clinical Research Professionals (ACRP) Fall Symposium. On September 20th, we are hosting a joint meeting with the San Diego Regulatory Affairs Network (SDRAN). We are also planning a free webinar on October 2nd to discuss the RFP (request for proposals) process. Many thanks to Susan Vintilla-Friedman, Susan Chang, Lauren Sobocinski and Valerie Breda for participating in these events.

Please join me in thanking Sally Altman for all of her wonderful contributions to our FDA news column in our monthly newsmagazine over the past 2 years. Thank you, Sally! With the passing of the baton, we welcome our new FDA news reporter, Amanda Fisher, to our newsmagazine team. Please check out her first report in this issue.

Also included in this September issue, Dikran Toroser has provided an informative review of best practices and guidance for protecting patient and clinical trial participant rights in peer-reviewed publications. Wim D'Haeze always does a great job keeping us updated about what is happening in European regulatory news. Rebecca Anderson has written an amusing piece about the media discussions on the lack of water this Summer. We thank Ellen Klepack for the pharmacovigilance updates and Irene Yau for giving us some Fall reading suggestions and updates about job postings in our area. If you are looking for a book to read online, check out Project Gutenberg highlighted on the backpage.

We like being active and engage our Chapter community, so please let us know if you would like to help plan an AMWA Pacific Southwest Chapter event in your area. If you wish to contribute to our newsmagazine, please contact our star Editor, Ajay K Malik (ajay@amwa-pacsw.org).

See you in Memphis!
Donna

Donna Simcoe, MS, MS, MBA, CMPP
President, AMWA Pacific Southwest Chapter

AMWA Pacific-Southwest Chapter warmly welcomes our new members

Jessica Fowler – Los Angeles, CA

Alayna Mackay – San Diego, CA

Osnat Ben-Shahar – Goleta, CA

Salil Sheth – Diamond Bar, CA

Angela Tetmeyer Yazici – La Jolla, CA

Beach By JessicaCooper1231 (www.morguefile.com/creative/JessicaCooper1231). Image URI: http://mrg.bz/U0Q6uA

List courtesy of Gail Flores, PhD, AMWA-PacSW membership coordinator.

PICTURE: Seattle Daily Times news editor quarters - 1900. Via Wikipedia (http://en.wikipedia.org/wiki/Editing#mediaviewer/File:Seattle_Daily_Times_news_editor_quarters_-_1900.jpg)

EDITOR'S desk:

The Language Arts of Medical Writing

The practice of medical writing is more of an art than a guidance and regulation-driven enterprise. It lends itself to myriad shades and subtle nuances in the form of word choices and sentence structures which creates a canvas with power to define us as individuals and as professionals. This makes medical writing no different from any other consumer-directed writing, for example, food writing business.

Dan Jurafsky, the Professor of Lingusitics and Computer Science at Stanford, researching the language of restaurant menus and consumer reviews, wrote recently in *Financial Times*,[1] "We are surrounded by the language of food, words that offer a window into our psyche, our finances and our society"—high-end restaurants presuppose good food and sprinkle fancy (foreign and unpronounceable) words in their menu, while middle-priced restaurants (suffering from status anxiety) use surfeit of adjectives. All food writing is directed towards striking a balance between loosening the grip of consumer on their wallet while stealthily providing a satisfaction (pleasure or ego-boost) in return. Like the food writing business, medical writing is also directed to “tough” consumers, better called “audience”— researchers, physicians, FDA or other regulatory bodies, and informed patients and advocacy organizations. Satisfying so many picky paletes using words is truly an art.

Like all great artists, the art (of medical writing) is best learned from pros and requires constant practice. The upcoming AMWA Annual Conference in Memphis has many workshops and open sessions under Writing/Editing track to help build the very foundation of our arts.

WS-20 • Basic Grammar I
WS-36 • Basic Grammar II and Usage
WS-55 • Usage: Choosing the Right Word for the Job
WS-53 • Punctuation for Clarity and Style
WS-05 • Sentence Structure and Patterns
WS-52 • Outlining for Writers and Editors
WS-37 • Effective Paragraphing
WS-23 • Establishing Style: Exploring and Developing In-House Guides
OS-39 • Hands On: Using Styles in Microsoft Word to Make Your Work Shine
WS-48 • Advanced Writing
OS-40 • How to Use the 3 Ps of Powerful Content: Plain, Personal, Possible
T-07 • Editing and Proofreading Your Own Work
WS-01 • Microediting
WS-34 • Macroediting

The pages of this newsmagazine, *Postscripts*, also carry magic tricks and "insider information" to take our arts to the next level. MOOCs like *Corseara* and *edX* are other great sources to explore for free.

Just over 200 years ago, Samuel Johnson in his book, *A Grammar of the English Tongue*, wrote: "Grammar, which is the art of using words properly, comprises four parts: Orthography, Etymology, Syntax, and Prosody."[2] These ‘parts’ are the crayons that give shape to our collages.

—Ajay K Malik, PhD

[1]The secret language of food by Dan Jurafsky. Financial Times. August 22. 2014. Available at http://www.ft.com/cms/s/2/82f41202-27f3-11e4-ae44-00144feabdc0.html

[2]A Grammar of the English Tongue by Samuel Johnson. 1812. Available free at http://www.gutenberg.org/ebooks/15097

Protecting Research Participants' and Patients' Rights in Publications

Dikran Toroser, PhD, CMPP, Amgen Inc.

"The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject…"
World Medical Association[1]

Rules for protecting the rights of research participants and patients in publications have their foundations in the Nuremberg Code,[2] the World Medical Association's Declaration of Geneva,[3] and the World Medical Association's Declaration of Helsinki.[1] Today, protection of such rights are governed by national and international guidelines.[4] Editors and authors have an ethical duty to follow these principles as well as to honor individuals' rights to privacy.

Ethical Review. To protect the safety and dignity of individuals who participate in research, institutions and grant agencies require that any study involving human participants be reviewed and approved by an institutional review board (IRB). The National Institutes of Health (NIH) defines *a human subject as "a living individual about whom an investigator obtains either (1) data through interaction or intervention with the individual, or (2) identifiable private information."* The NIH also identifies several research categories involving human participants as exempt from IRB review provided the study does not expose participants to physical, social, or psychological risks.

Journal Policies and Procedures. Journals should require authors to state explicitly in the Methods section of the manuscript that an appropriate independent ethics committee or IRB approved the study protocol or determined that the investigation was exempt from such approval and why. If the study protocol was approved by several ethics committees/IRBs, as would be expected in a multicenter study, it is appropriate to note that review and approval were conducted by the ethics committees/IRBs of all participating centers/institutions. Journals should also require authors to indicate that informed consent was obtained from all participants.

Reports of Unethical Studies. The past publication of unethical research does not justify its continued practice. In the case of missing IRB and consent information, the editor should ask the author why such information is not reported. The author may have neglected to report this information or a manuscript may contain a secondary analysis and the information about IRB approval and/or informed consent was reported in the primary publication. If an author refuses to address concerns about such ethical requirements, the editor should notify the author's institutional or funding authority.

Patients' Rights to Privacy and Anonymity. *Privacy* is a state or condition of limited access to matters of a personal nature, as well as an individual's right to control such access. When individuals grant others access to themselves (eg, during a patient-clinician encounter), the individuals are exercising their right to privacy, but they are not waiving this right.

Historically, medical journals have taken steps to protect patients' rights to privacy and anonymity. Only those details essential for understanding and interpreting a specific case report or case series are usually provided. However, patients have occasionally recognized descriptions of

themselves in medical articles. For accepted manuscripts, when informed consent has been obtained, journals should indicate as such in the Methods section.

> **Methods**: This investigation was approved by the medical center's institutional review board. The 12 patients in this case series provided written informed consent for the investigation.

At JAMA, whether a manuscript contains identifiable patient information is determined on a case-by-case basis.

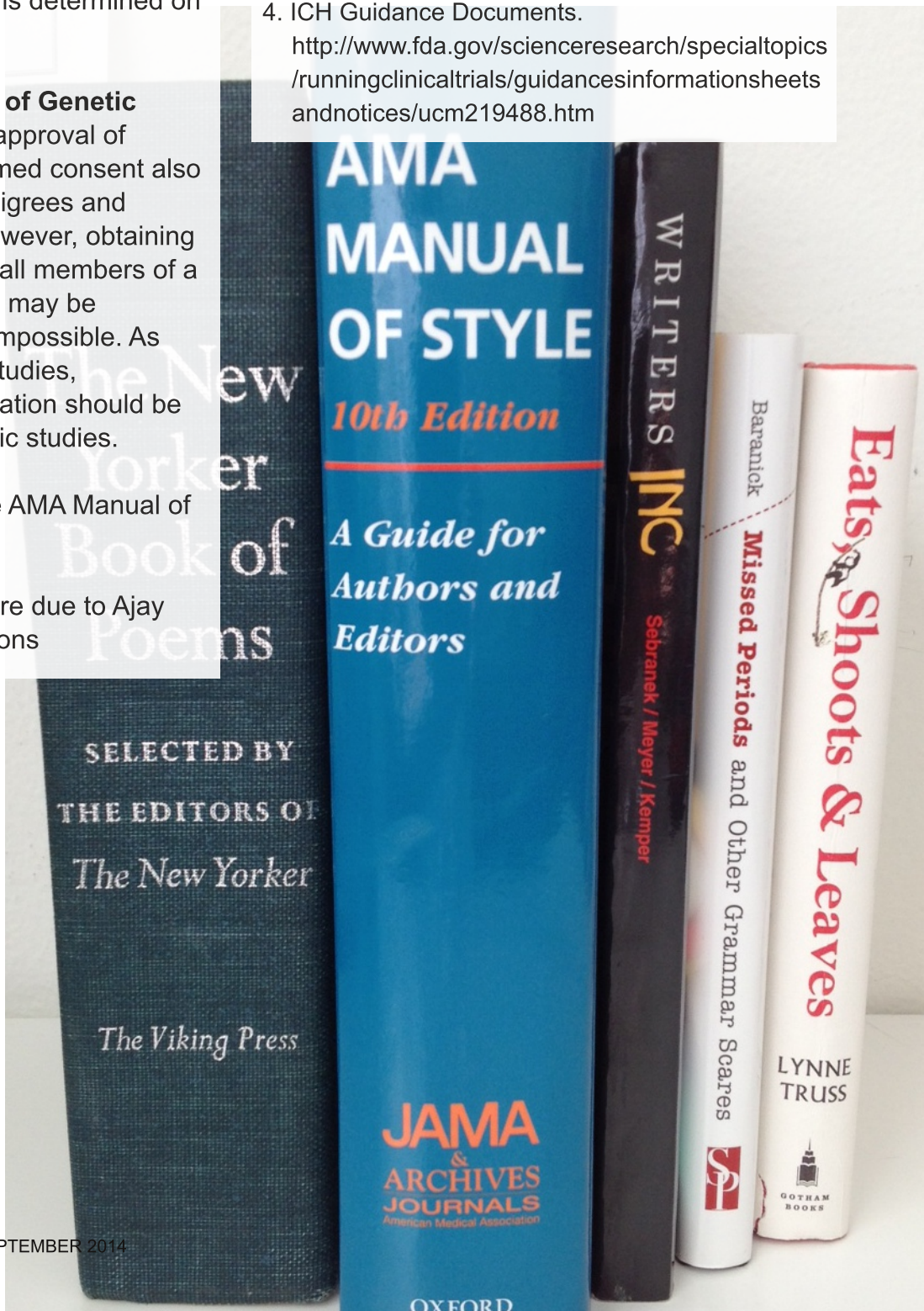
Rights in Published Reports of Genetic Studies. The rules for ethical approval of studies and for obtaining informed consent also apply to genetic studies of pedigrees and population-based samples. However, obtaining written informed consent from all members of a large pedigree (many of whom may be deceased) may be difficult or impossible. As with reports of other types of studies, nonessential identifying information should be removed from reports of genetic studies.

Also see pages 226-235 of the AMA Manual of Style 10th edition.

Acknowledgement: Thanks are due to Ajay Malik, PhD, for useful discussions

REFERENCES

1. World Medical Association. Declaration of Helsinki. Accessed August 9, 2014 http://www.wma.net/en/30publications/10policies/b3/17c.pdf
2. The Nuremberg Code. JAMA. 1996;276(20):1691.
3. World Medical Association. Declaration of Geneva. http://www.wma.net/en/30publications/10policies/g1/ Accessed August 9, 2014
4. ICH Guidance Documents. http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm219488.htm



The Water Whisperer

By Rebecca J. Anderson, PhD

Gwyneth Paltrow recently made news (ok, it was on Comedy Central) for asserting that water can be damaged if it's exposed to negative emotions. She was persuaded by the books of Masaru Emoto, a certified Doctor of Alternative Medicine and author of *The Secret Life of Water* and other soggy tales. Swallowing his views like a Friday night boozer, Gwyneth is "fascinated by the growing science behind the energy of consciousness and its effects on matter." Through selective observations and uncontrolled experiments, Emoto concludes that negative (or positive) words, emotions, and music can influence the crystalline structure of water. If that's true, then perhaps a bottle of damaged water should be relabeled "H_2Woe" or "traumatic stress dis-water."

To their credit, Gwyneth and Masaru are calling attention to a natural resource that no one worries about until there is too little of it. Here on the west coast, people are responding to the water crisis—ok, we're kicking and screaming, but we're responding. Elected officials are using more of a stick than a carrot, hoping that higher water rates for heavy users will incentivize conservation. (Yellow is mellow, brown goes down.) But affluent homeowners with extensive landscaping are simply digging deeper wells, trucking in water, and threatening to build their own desalination plant. The rest of us have to, well, suck it up, while looking longingly to the east, where people have the opposite problem.

The Midwest has been hit with so much rain that the Land of a Thousand Lakes will soon become Lake Minnesota, the sixth Great Lake. Coastal cities are flooded so regularly that they are taking tips from Amsterdam and Venice: commuting by canal.

Taking the US as a whole, the problem is not a matter of supply outstripping demand but rather an imbalance of resources. I advocate a simple solution: redistribution. If engineers can dig the Keystone Pipeline from Canada to Texas, surely they can also run an aqueduct from the flooded prairies to the arid Westlands. Everybody wins.

But Gwyneth and Masaru may have stumbled upon an even simpler, more economical solution. (Masaru says, "Sometimes fantasy is the best way to get a clear picture of reality.") Perhaps all we need to do is think positive thoughts: send seductive vibes and lure those distressed water molecules to the less saturated skies out west. They can patter on sun-bleached beaches and flow through pristine canyons. They can hug mountaintops and tumble down breathtaking ski slopes. They can mingle with their ocean spray cousins and bathe swaying palm fronds. And most of all, they will be welcomed, not cursed. What traumatized H_2Woe molecule wouldn't migrate toward that?

What's Up(!) . . . at FDA

By Amanda Fisher, PhD

During the month of August the FDA released four guidances to its website and advised consumers not to purchase products that claim to prevent or cure Ebola virus. Batches of Cubicin and Dianeal dialysis solution were voluntarily recalled after reports of particulate contamination. In addition, the FDA approved new drugs with indications including insomnia, Gaucher disease type 1, and multiple sclerosis. Two new drugs were approved to treat type 2 diabetes and Orbactiv is the third new antiobiotic to be approved this year to treat acute bacterial skin infections. September will be a busy month at the FDA with eight drug advisory committee meetings and several workshops and conferences.

Selected FDA Announcements

Date	Announcement
8-4-14	The FDA released a new guidance for industry, *Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* (draft).[1]
8-5-14	The FDA released a new guidance for industry, *Upper Facial Lines: Developing Botulinum Toxin Drug Products* (draft).[2]
8-7/8-14	Cubist Pharmaceuticals issued a voluntary recall of CUBICIN® (Daptomycin for injection) 500 mg in 10 mL single use vials because of potential contamination with glass particulates. The affected lots were sold between 2011 and 2014.[3] An additional nine lots are being recalled due to complaints of foreign particulate matter in reconstituted vials.[4]
8-13-14	The FDA released a final guidance for industry, *Immunogenicity Assessment for Therapeutic Protein Products*[5] and a draft guidance for industry, *Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products— Considerations, Content and Format*.[6]
8-14-14	The FDA warned consumers not to purchase fradulent products online that claim to prevent or treat the Ebola virus. The agency reminded consumers that there is currently no FDA-approved vaccine or drug to prevent Ebola.[7]
8-15-14	Baxter International Inc. issued an additional voluntary recall of Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution due to the presence of particulate matter, including oxidized stainless steel, garment fiber, and PVC particulates. The affected lots were distributed between May, 2014 and July, 2014.[8]

Selected FDA Approvals

Drug	Indication	Company
Belsomra®	Insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.[9]	Merck
Cerdelga™	Gaucher disease type 1 patients who are not CYP2D6 ultra-rapid metabolizers.[10]	Genzyme
Invokamet™	Type 2 diabetes mellitus not adequately controlled on a regimen containing metformin or canagliflozin.[11]	Janssen
Jardiance™	Type 2 diabetes.[12]	Boehringer Ingelheim
Orbactiv™	Acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms.[13]	Medicines Co.
Plegridy™	Relapsing forms of multiple sclerosis.[14]	Biogen Idec Inc.

September 2014 Advisory Committee Meetings	
9-3-14	General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee[15]
9-4-14	Nonprescription Drugs Advisory Committee - sunscreen active ingredients[16]
9-9-14	Cardiovascular and Renal Drugs Advisory Committee - NDA submitted by Forrest Laboratories[17]
9-11-14	Endocrinologic and Metabolic Drugs Advisory Committee - NDA submitted by Novo Nordisk[18]
9-12-14	Endocrinologic and Metabolic Drugs Advisory Committee - NDA submitted by NPS Pharma[19]
9-17-14	Joint Mtg of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee - testosterone replacement therapy[20]
9-18-14	Cellular, Tissue and Gene Therapies Advisory Committee - research program updates[21]
9-23-14	Pediatric Advisory Committee - pediatric-focused safety reviews[22]

September 2014 Meetings, Conferences, and Workshops	
9-5-14	Workshop on the Clinical Development of Drugs to Prevent Infections Caused by *Staphylococcus aureus* in the healthcare setting[23]
9-5-14	Advancing the use of Biomarkers and Pharmacogenomics[24]
9-10/11-14	Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated with Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting[25]
9-16/17-14	FDA/PQRI Conference on Evolving Product Quality[26]
9-18/19-14	FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Conference[27]

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm [Link]
- For additional information on recalls, market withdrawals, and safety alerts, see http://www.fda.gov/Safety/Recalls/default.htm [Link]
- For information on current drug shortages and drugs to be discontinued, see http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm [Link]
- For Orange Book drug product list additions or deletions, see http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm [Link]

[1]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM407844.pdf [Link]
[2]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM407983.pdf [Link]
[3]http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm408677.htm [Link]
[4]http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm408934.htm [Link]
[5]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM338856.pdf [Link]
[6]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM109739.pdf [Link]
[7]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm410086.htm [Link]
[8]http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm410307.htm [Link]
[9]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm409950.htm [Link]
[10]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm410585.htm [Link]

[11]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails [Link]
[12]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm407637.htm [Link]
[13]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm408475.htm [Link]
[14]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails [Link]
[15]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm407136.htm [Link]
[16]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm407137.htm [Link]
[17]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm406953.htm [Link]
[18]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm407894.htm [Link]
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[24]http://www.fda.gov/Drugs/NewsEvents/ucm407688.htm [Link]
[25]http://www.fda.gov/Drugs/NewsEvents/ucm401452.htm [Link]
[26]http://www.fda.gov/Drugs/NewsEvents/ucm408073.htm [Link]
[27]http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm409987.htm [Link]

FDA Regulates the Safety of Packaged Ice

The average American buys four bags of packaged ice each year, 80 percent of it between Memorial and Labor Day1. The Food and Drug Administration (FDA) regulates packaged ice in interstate commerce as a food, just like other foods. And like other foods, packaged ice must be produced according to FDA's regulation for Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food.

Read more here:
http://www.fda.gov/Food/FoodborneIllnessContaminants/BuyStoreServeSafeFood/ucm197586.htm

What's Up(!) . . . at EMA

By Wim D'Haeze, PhD

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (26 JUL 2014 THROUGH 29 AUG 2014)

The alerts listed below cover the period from July 26, 2014 through August 29 2014. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

• Draft guideline on influenza vaccines: non-clinical and clinical module (open for publication consultation)[a]

REPORTS/PAPERS

• None to report

GENERAL ANNOUNCEMENTS

• Europe to boost cooperation with international partners on generics.[b]

APPROVALS/REFUSALS

Compound	Indication/Use[1]	Applicant	Advice [Note]
None	NA	NA	NA

[a]As per recommended approval.

Note: "positive" or "negative" opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

WEBLINKS

[a].http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500170300&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [Link]

[b].http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/08/news_detail_002156.jsp&mid=WC0b01ac058004d5c1 [Link]

Safety Sentinels: Pharmacovigilance Issues and News

By Ellen Klepack, PharmD

Hydrocodone Combination Products (HCPs) to Be Moved to Schedule II

On August 22, 2014, the U.S. Drug Enforcement Administration (DEA) published a Final Rule in the Federal Register that will move hydrocodone combination products (HCPs) from Schedule III to Schedule II, resulting in additional prescribing and dispensing restrictions.[1] This rule is part of an effort to curb opioid diversion and abuse. The rule reclassifying HCPs will go into effect on October 6, 2014.

Hydrocodone Most Prescribed Medication in the United States

Hydrocodone is a widely prescribed opioid analgesic used to treat moderate to moderately severe pain and also acts as an antitussive to treat cough. It is available in many different formulations and combined with other substances such as non-narcotic analgesics, antihistamines and anticholinergics (common U.S. trade names include Vicodin, Lortab, Vicoprofen, Tussigon, Tussionex). According to an IMS health report, hydrocodone/acetaminophen was the most prescribed medication in the United States in 2013 with close to 130 million prescriptions dispensed.[2]

The Controlled Substances Act

The Controlled Substances Act was passed as part of the Drug Abuse Prevention and Control Act of 1970. Substances that have a potential for psychological and physical dependence and abuse are placed into one of five categories and are restricted accordingly. Substances placed in Schedule I have no accepted medical use and have a high abuse and dependence potential (eg, heroin, LSD, marijuana). Schedules II-IV contain substances for which there is an accepted medical use but also the potential for addiction and abuse. Schedule II contains substances with the highest level of abuse/addiction potential and Schedule IV is the least of the five categories. At the time the Controlled Substances Act was passed, hydrocodone by itself was classified as a schedule II controlled substance while HCPs were classified as schedule III.

Reclassification of HCPs

Reclassifying HCPs to a more restrictive Schedule II was initiated by the petition of a physician in 1999.[3] Based on that petition, the DEA submitted a request in 2004 to the Health and Human Services (HHS) to provide a medical and scientific evaluation of available data and recommendation for rescheduling HCPs.[1] In 2008, the HHS recommended that HCPs remain as Schedule III base on their evaluation. In 2009, the DEA requested that HHS provide another evaluation of available data and a recommendation based on their updated analysis. In January 2013, the FDA held a public Advisory Committee meeting and voted 19 to 10 in favor of placing HCPs into Schedule II. In December 2013, HHS submitted their updated evaluation to the DEA with a recommendation in favor of moving HCPs to Schedule II. Based on these recommendations and additional analyses, the DEA published a Proposed Rule to change the scheduling of HCPs in the *Federal Register* on February 27, 2014, which was followed by publication of a Final Rule on August 22, 2013.

Reaction to the Schedule Change

When the Proposed Rule was published in the *Federal Register*, the DEA received 573 comments from a variety of individuals. Fifty-two percent (52%) (298 comments) were in support or supported with qualification the movement of HCPs into Schedule II as a way to help control the epidemic of opioid abuse in the United States.[3] Forty-one percent (41%) (235 comments) opposed the rescheduling and 7%

(40 comments) did not include a definite position.[3] Concerns from those opposed to the rule change included its impact on prescription practices, patient access to medication, impact on long term care facilities, the additional workload for providers and pharmacists, added costs for patients and the health care system, supply issues due to stricter storage and handling laws, and concerns that rescheduling HCPs will not prevent abuse or diversion.

Sources

1. United States Drug Enforcement Administration [news release]. DEA Public Affairs; August 21, 2014. http://www.justice.gov/dea/divisions/hq/2014/hq082114.shtml. Accessed August 27, 2014.
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Fall Reading List

Irene Yau, PhD, Allergan, Inc

As summer draws near to a close and we try to squeeze in one last bbq grilling session or one more poolside layout, let's gear up for fall and add some fall readings to our book list. Here are three books on my list that I want to read.

Lean In: Women, Work, and the Will to Lead by Sheryl Sandberg

Author Sheryl Sandberg has an impressive resume as current chief operating officer of Facebook and former vice president of operations of Google. Her book is about women in the workplace, or specifically what women do and don't do in the workplace that hinders their career growth. She encourages women to "lean in" at meetings and really take on challenges and risk rather than discounting themselves from the beginning. I am most interested in what she has to say about the work-family balance that I feel many women face and view as a dilemma.

Brick by Brick: How LEGO Rewrote the Rules of Innovation and Conquered the Global Toy Industry by David C. Robertson

I'm sure many of us have fond memories of playing with buckets of LEGOs as a child. Surprisingly, the company was on the verge of bankruptcy 2003. You certainly wouldn't be able to know that now with the blockbuster release of The Lego Movie, and the crowded Lego stores at the local mall. And that's what draws me to this book – the plight of a beloved toy company that needed to innovate to succeed. As the author reveals, their first strategy of innovation was too extreme and they needed to actually think back *into* the box with their innovation. While we may not own a large corporation facing bankruptcy, we will all face trials in life and we will have a choice in how we respond to them.

Quiet: The Power of Introverts in a World That Can't Stop Talking by Susan Cain

Do you know if you are an extrovert or introvert? What makes you one or the other isn't necessarily how social you are, but in which situation you draw energy from. If you feel recharged after being alone for a Saturday afternoon, then you may be an introvert. Cain writes that in a society that increasingly values extroverts, from the classroom to the workplace, the qualities of introverts can be undervalued and dangerously so. The author gives examples of famous introverts, the science behind introverts/extroverts, and ends with practical applications. I am an introvert and what draws me to this book is that the author, an introvert as well, highlights the strengths of introverts and how to use them to an introvert's advantage rather than trying to change the behavior of introverts.

I would like to compile a list of book recommendations from our chapter members. E-mail me (employment-coordinator@amwa-pacsw.org) your Fall Reading list, along with why you want to read this book or why you would recommend it so I can compile a list for an upcoming issue!

September 2014 Job Listing

Compiled by Irene Yau, PhD, Allergan, Inc.

Senior Manager – Hemophilia Medical Communication
Baxter, Los Angeles

Scientific Writer
Thermo Fisher Scientific, Carlsbad

Senior Manager, Medical Writing
Ambit Biosciences, San Diego

Medical Information Associate
Avanir, Aliso Viejo

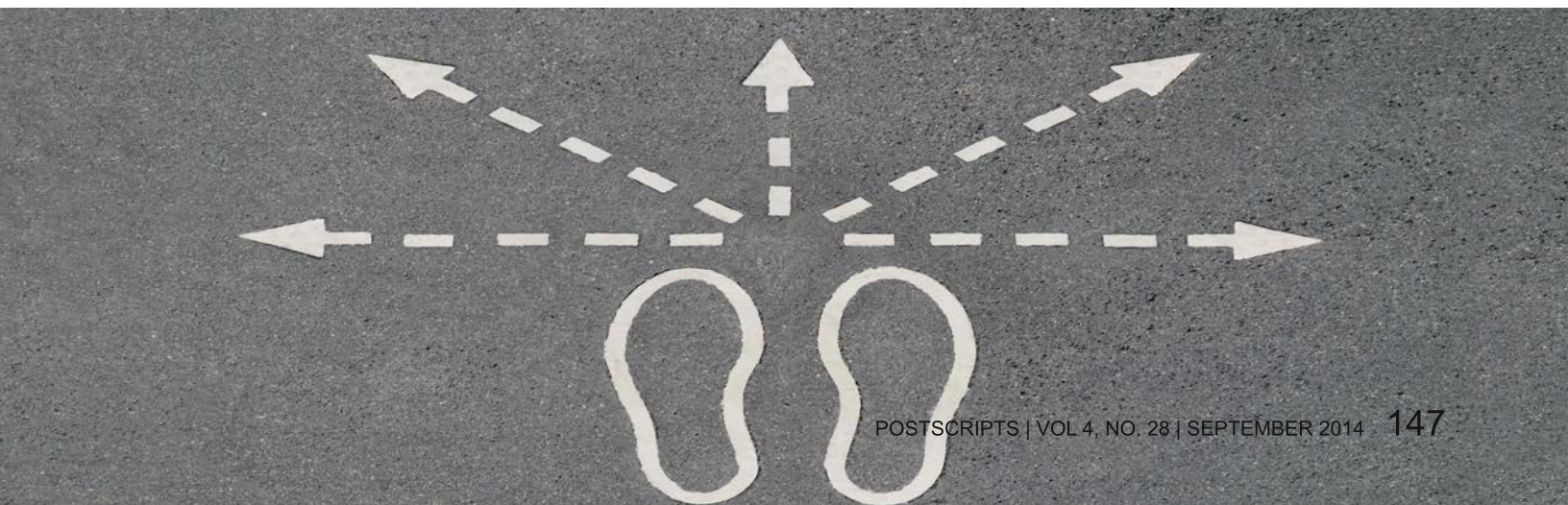
Manager, Medical Communications
Intercept Pharmaceuticals, San Diego

Sr./Principal Medical Writer
Intercept Pharmaceuticals, San Diego

As a reminder, complete Job Listings are available for current, interested members and are available through the following ways:

- Job openings are sent out ~monthly through the jobs mailing list
- Job listings will be posted periodically through our LinkedIn SubGroup, AMWA Pacific Southwest Chapter, so be sure to join the group

Please e-mail employment-coordinator@amwa-pacsw.org if you'd like to receive job listings or share any job leads with the group and it will be added to the job listings.



Michael S Hart, the Creator of Project Gutenberg

"Learning is its own reward. Nothing I can say is better than that."
-Michael S Hart

Michael Hart and Gregory Newby at HOPE Conference. Picture by Marcello. (via Wikipedia Michael S Hart). CC BY-SA 3.0

Michael Stern Hart (b. March 8, 1947; d. September 6, 2011)

Michael Hart invented eBooks when he typed a copy of Declaration of Independence in a network connected mainframe computer at the University of Illinois at Urbana-Champaign (where he was a student) in 1971 and shared it with over 100 people, ages before Kindle, Nook and App Stores became mainstream.

He is best known today as the founder of Project Gutenberg—the largest collection of free eBooks in the world with 45,000 eBooks and counting. He said that there are two things in the world that are truly and totally free, the air we breathe and the texts on Project Gutenberg.

Read more about Michael's life here:

Obituary for Michael Stern Hart. *Project Gutenberg*. http://www.gutenberg.org/w/index.php?title=Michael_S._Hart

Michael Hart, a Pioneer of E-Books, Dies at 64. By William Grimes. *New York Times*. September 8, 2011. http://www.nytimes.com/2011/09/09/business/michael-hart-a-pioneer-of-e-books-dies-at-64.html

Project Gutenberg creator Michael S. Hart dies at 64. *Washington Post*. By Emily Langer. September 8, 2011. http://www.washingtonpost.com/local/obituaries/project-gutenberg-creator-michael-s-hart-dies-at-64/2011/09/08/gIQA1DMFDK_story.html

—Editor